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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/090,672	06/04/1998	TETSUYOSHI ISHIWATA	766.21	4139

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	31

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Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No. 09/090,672	Applicant(s) Ishiwata et al.
	Examiner Joseph Woitach	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 12, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 18, 19, 22, and 23* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *23* is/are allowed.

6) ☒ Claim(s) *1, 18, 19, and 22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *29, 30*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 12, 2002, paper number 28, has been entered.

DETAILED ACTION

This application is a continuation in part of PCT/JP97//04468, filed December 5, 1997, which claims benefit to foreign application HEI. 8-325763, filed December 5, 1996 in Japan.

As requested in Applicants' request for continued examination the after final amendment filed September 26, paper number 26, has been entered. Claims 4 and 5 have been canceled. Claims 1 and 22 have been amended. Claim 23 has been added. Claims 1, 18, 19, 22 and 23 are pending and currently under examination.

Claim Objections

Claim 22 objected to because continuous was mispelled 'continuos' is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 1, 18 and 19 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

Additionally, claims 1,18, and 19 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described is withdrawn.

Amendments to the claims deleting the term 'identity' has obviated the basis of the rejection. As noted in the previous rejection, support for sequences which are 'homologous' and which can hybridize are set forth (page 7). Further, the specification provides support for isolated DNAs comprising a nucleotide sequence identical to contiguous 10 to 50 residues selected from the nucleotide sequences represented by SEQ ID NOs:1-6 and 9-12 in accordance

with the teachings from the specification (e.g. p. 8, lines 1-4). However, 10 to 50 residues of identity would not constitute 60% or 95% identity over the entire length of the given SEQ ID NOs recited in the claim.

Claims 1, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is broadly drawn to isolated nucleic acids (and compositions with intended uses for therapeutic and diagnostic use, claims 18 and 19) of isolated DNAs comprising the nucleotide sequences of SEQ ID NOs:1-6 and 9-12 and isolated DNAs hybridizing to such. The basis of the instant rejection focuses on the embodiments of the enormous number of polynucleotide sequences which would hybridize to SEQ ID NOs:1-6 and 9-12, however have no relationship to IgA nephropathy. As evidenced by unrelated prior art disclosures revealing matches of at least 17 nucleotides to any of the given 10 SEQ ID NOs examined in the instant application (see previous office action, 35 USC 102 rejection), the claims encompass nucleic acid embodiments disclosed in the prior art from unrelated organisms or with no connection to IgA nephropathy, particularly since any given 100-1000 base pair sequence would be expected to contain multiple matches to unrelated nucleotide sequences containing at least 10 continuous residues. The specification does not teach how to use nucleic acids lacking the ability to discriminate between

products exemplified by SEQ ID NOs 1-6 and 9-12 that may be upregulated in IgA nephropathy and unrelated products comprising sequences capable of hybridizing to SEQ ID NOs 1-6 and 9-12, given the stringency conditions recited in claim 1. The specification does not provide a basis or a methodology for predicting *a priori*, absent undue experimentation, those embodiments embraced by the scope of the claims that have a patentable utility in i.e. diagnostics or pharmaceutical, in accordance with the teachings in the specification. The courts have stated that: 'The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of characteristics. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F 3d at 1324, 63 USPQ2d at 1613 (Fd Cir 2002).

The court has also addressed the issue of what constitutes adequate written description of a claim to a broad genus of sequences Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated: 'In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or

"mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, indicating generally that a variant protein maintains a property of the parent protein generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Examiner would concede that the artisan can make sequences capable of hybridizing to SEQ ID NOs 1-6 and 9-12 with the stringency conditions recited in claim 1 and test the variants for a specific properties, however this is not sufficient to meet the written description

requirement. The courts have stated that adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). Therefore, while one may make and test all the possible variant sequences encompassed by the claim, the specification fails to provide the necessary description to which of all these possible variants would retain any function of the parent molecule, in particular sequences which are associated with IgA nephropathy

In analyzing whether the written description requirement is met by disclosure of a sufficient number of species, it is first determined whether the whether a representative number of species have been described by their complete structure. In the instant case the claims encompass an enormous number of variant polynucleotide sequences which are only defined by their ability to hybridize, however only one SEQ ID NO of each possible species is disclosed. With the limited information disclosed in the specification, the artisan does not have the necessary guidance to whether any other sequence besides SEQ ID NOs: 1-6 and 9-12 exist in nature or that any variant would have a useful functional property related to IgA nephropathy. In the instant case, the single example of one sequence as set forth in each of the specific SEQ ID NOs does not provide adequate disclosure for the infinite number of variant sequences encompassed by the claims.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In the instant case, the recitation of only sequence homology without any other functional description, does not provide adequate description of the polynucleotides claimed. Thus, the limited disclosure of single species of each of the specific SEQ ID NOs in the instant specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the huge genera recited and encompassed by the claims at the time the application was filed. Thus, it is concluded that the written description requirement under 35 U.S.C. 112, first paragraph, is not satisfied for the claimed genera.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 18, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1 is unclear and confusing in the recitation of 'an isolated DNA which hybridizes with the isolated DNA immobilized', because the only antecedent basis for 'the isolated DNA' is what is being instantly claimed, however there is no indication that it is immobilized. The claim

is circular and appears to be claiming any polynucleotide which would hybridized to itself and shares homology with SEQ ID NOS 1-6 and 9-12, however it is unclear how one can measure hybridization without first having the claimed DNA molecule. With respect to % homology, if the isolated DNA is the same as that which is immobilized, it is unclear how it can have any less than 100% homology since they are the same sequences. Further, the metes and bounds of 'homology' are indefinite because the specification does not specifically define the term homology, and thus homology can be calculated by various means. The claims are indefinite because metes and bounds of the claims are dependent on the method used to determine homology and can change depending on how what program with its various parameters the artisan would use to determine percent homology. Dependent claims 18 and 19 are included in the basis of the rejection because they fail to further clarify the basis of the rejection. More clearly setting forth the DNA molecule which is immobilized may obviate the basis of the rejection.

Claim 22 is unclear and incomplete because practicing steps (a)-(c) will not result in 'detecting mRNA whose expression level increases' as required by the preamble because it will detect any mRNA amplified by the primers encompassed by the SEQ ID NOs. The method of RT-PCR set forth in the claims is used to detect the presence of a mRNA in a sample, however it will not distinguish any change, either increase or decrease, in the mRNA from a sample. More clearly setting forth an additional step(s) wherein mRNA levels are quantified or amending the

preamble to indicate specifically what mRNAs are being detected would obviate the basis of the rejection.

Conclusion

Claim 23 is allowed. Claims 1, 18, 19, 22 and 23 are free of the art of record because the art fails to teach polynucleotide sequences encompassed by the instant claims. Further, the art fails to teach that the polynucleotide sequences correlate to genes which demonstrate an increased expression in the leukocytes of patients suffering from IgA nephropathy, however the claims are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

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